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SITTING PRESSURE-MAPPING OF THE BUTTOCKS REGION OF ELDERLY PEOPLE WHO USE WHEELCHAIRS FOR LOCOMOTION

by

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Bachelor of Science, University of North Dakota, May 1992
Bachelor of Science in Physical Therapy
University of North Dakota, 2002

A Scholarly Project

Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine

University of North Dakota

in partial fulfillment of the requirements

for the degree of

Master of Physical Therapy



Grand Forks, North Dakota May 2003 This Scholarly Project, submitted by Brian A. Rud in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

(Graduate School Advisor)

(Chairperson, Physical Therapy)

PERMISSION

Title

Sitting Pressure-Mapping of the Buttocks Region of Elderly

People Who Use Wheelchairs for Locomotion

Department

Physical Therapy

Degree

Master of Physical Therapy

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ABSTRACT

Elderly people who spend multiple hours in a wheelchair are prone to skin breakdown of the buttock and leg regions. Pressure relief of these areas can help prevent skin breakdown and can be acheived through the use of a wheelchair cushion, weight shifting, and positioning. Strategies for effective pressure relief can be found for individuals by utilizing pressure-mapping technology.

The purpose of this study was to identify if elderly wheelchair-dependent nursing home residents (n = 6) had adequate pressure relief of the buttock and leg regions. Pressures at the buttock and leg regions were measured with the FSA Pressure-Mapping device under four conditions: the currently utilized cushion and air, gel, and honeycomb cushions. In addition, patient education with the residents addressed weight-shifting techniques and proper wheelchair positioning.

For the six subjects, there was no significant difference in pressure relief across the four pressure-reliving cushions tested. Graphing of the results demonstrated that individuals responded differently to the various cushions.

Thus, the pressure-mapping device was helpful in identifying the cushion providing the best pressure relief for each individual subject and subjectively helped in identifying effective weight-shifting techniques and proper positioning in

the wheelchair. Further research is needed to assess the long-term effectiveness of a pressure-mapping device for the prescription of wheelchair cushions and pressure-relief education in a nursing home setting.

CHAPTER I

INTRODUCTION

Wheelchairs provide a means of locomotion for many of the elderly people in nursing homes. It is estimated that there are approximately 600,000 elderly wheelchair users in the US nursing home setting. Many of these people will spend multiple hours in a wheelchair, which can potentially cause problems such as pressure sores and discomfort.

Pressures sores, also known as pressure ulcers, can be a significant health risk for the elderly nursing home residents and a staggering expense for the facilities. Treatment of pressure sores is very time-consuming and difficult. With better pressure relief for wheelchair-dependent people, sitting-acquired pressure sores can be avoided and, thus, the expense of treatments for them.

Pressure-mapping and pressure-relieving cushions are becoming more widely used tools in the prevention of pressure sores. Newer technology and better software programs have allowed for more accurate pressure readings. Ongoing research on the design of pressure-reliving cushions has also made an impact on the level of comfort and the decrease of pressure sore occurrence. By using the pressure-mapping device, the most adequate wheelchair cushion, weight-shifting techniques, and positioning can be found for each wheelchair user.

Purpose

The purpose of this study was to identify if elderly wheelchair-dependent nursing home residents had adequate pressure relief in the buttock and leg regions. Potential pressure problems were addressed by education of weight-shifting techniques, proper wheelchair positioning, assessment of the current cushion, and evaluation of three pressure-reliving wheelchair cushions: the air, gel, and honeycomb cushions. These interventions should help present discomfort and sitting-acquired pressure sores from occurring. The research questions addressed were: 1) Are the wheelchair cushions provided for the Larimore Good Samaritan Nursing Home (LGSNH) residents adequate for pressure relief? 2) What type of pressure-reliving wheelchair cushion provides the most adequate pressure relief for elderly nursing home residents, the air, gel, or honeycomb cushion? 3) With proper instructions and education, can the nursing home residents decrease pressure by proper positioning and weight shifting?

Significance

Pressure relief of the buttock and leg regions is very important in the prevention of sitting-acquired pressure sores and discomfort in elderly nursing home residents who use a wheelchair for locomotion. Physical therapists are often involved in the assessment and treatment of people who are in wheelchairs and need relief from pressure and discomfort. The results of this study may help provide physical therapists and other health professionals with evidenced-based research to assist in choosing the most appropriate pressure-relieving wheelchair

cushion available for the elderly nursing home residents or other populations.

The LGSNH residents, their family members, and health care providers will also benefit by knowing how to help prevent sitting-acquired pressure sores.

CHAPTER II

LITERATURE REVIEW

The use of pressure-mapping systems has become an integral part of the prescription of pressure-reliving devices for those people who are susceptible to skin breakdown. Pressure-mapping devices have been around for many years.² They have been used in research and design of pressure-reliving devices as well as in the prescription of the most appropriate wheelchair cushion for patients. Early pressure-mapping devices used a single-sensory that could only measure pressure at a single site.^{2,3} This made it difficult to measure large areas accurately. For example, when measuring pressures at the ischial tuberosities, the left and right would have to be measured separately. Today's technology has allowed for the development of computerized pressure-mapping systems with multisensors, which make this type of procedure easier and more reliable.

There are several computerized pressure mapping systems available today.^{2,4} The more well-known ones are the Vista Medical Force Sensing Array (FSA), Winnipeg, Manitoba; Crown Therapeutic Xsensor, Bellville, III; TekScan, Boston, Mass; Talley/Oxford, Lansing, Mich; Q. A. Pad, Victoria, British Columbia; and ErgoCheck-Germany, Novel, Germany. These newer systems use different sized pressure-mapping mats for different applications and specialized software programs that can display data in real time from the sensing

mat. The data can also be saved as a "snapshot" measurement or a "movie" of the pressure measurements over time. The data can be replayed or individual frames can be printed at a later date. This allows for the continued monitoring of people who have pressure relief issues.

Today's pressure-mapping systems are being used for many different applications.⁴ These systems are used by researchers, medical equipment manufacturers and suppliers, industrial manufacturers, automotive manufacturers, retail businesses, the equestrian world, rehabilitation hospitals, acute care hospitals, nursing homes, and other facilities. Technology allows for the continued improvements in the equipment and software. Mats are modified to be more durable, pliable, and accurate. Computers process information faster and graphic displays are easier to read. The display generally consists of the pressure distribution map in color, statistical data, and a three-dimensional wire grid.³

Pressure distribution is checked by how many sensors of the mat are being used to register pressure. The more sensors being used represent a good distribution of pressure. According to literature recommendations, people who have pressures between 60 and 80 mmHg, with good pressure distribution and no active pressure sore problems, are at low risk for developing pressure sores. However, if pressures are 80 to 120 mmHg with uneven pressure distribution but no pressure sore problems, a different or new pressure-reliving cushion may be tried or pressure-relieving techniques can be learned and used throughout the day. If pressures are above 120 mmHg, with poor pressure

distribution regardless of pressure sore problems, an assessment should be done immediately and a prevention program started.

Many of today's elderly nursing home wheelchair users have issues with pressure relief and comfort. This stems from the lack of activity and mobility and the many hours spent in a wheelchair and/or a bed. With a lack of research regarding the pressure-reliving and comfort of wheelchair cushions for the nursing home population, finding a solution for these issues can be difficult and time-consuming. There are many different wheelchair cushions available in today's market. They can range from the expensive, approximately \$500, to the inexpensive, approximately \$10, but which ones work better for the nursing home population continues to be a question that needs more research. Previous studies have shown that there is no one wheelchair cushion that provides the best pressure relief for all people. Each person is different in body shape, contour, posture, height, weight, and mobility among other factors that can contribute to pressure and discomfort. To

A pressure ulcer risk assessment scale can be used to help identify people who are at risk for discomfort and development of pressure sores.^{7,8,11}

There are several scales of risk assessment that are being used worldwide. The quesion that then presents itself is which scale is appropriate to use for the nursing home population? This should be decided by the reliability and validity of the scale for that particular population. The most commonoy used scale for the nursing home population in the United States has been the Braden Scale.

Braden and Bergstrom⁸ developed the Braden Scale in 1987. The
Braden Scale consists of 6 categories: sensory perception, moisture, activity,
mobility, nutrition, friction and shear. 11,12 Scores can range from 6 to 23 with the
lower score being at a higher risk for the development of a pressure ulcer.

People who have a Braden Scale score of 15 to 18 are at low risk of developing
a pressure sore. 7,8 If the Braden Scale score is above 18, there is little risk at all.

If the score is 13 to 14, there is moderate risk; 10 to 12, there is high risk; and 9
or below, there is very high risk. Studies have been done on the Braden Scale to
test for its reliability and validity in the assessment of predicting risk for pressure
ulcers. 13,14 These studies have found it to be both reliable and valid in predicting
risk of pressure ulcer development. See Appendix E for an example of the
Braden Scale.

The Braden Scale has also been shown to help reduce the occurrence of pressure ulcers in nursing home residents when used on a regular basis.^{8,11,15} It allows for the identification of people who are at risk so an intervention program can be implemented. Pressure ulcer prevention is a key for the continued quality of life for the nursing home residents. It is believed that most pressure ulcers can be prevented.¹⁶

Prevention programs generally include pressure-relieving devices, such as mattresses and seat cushions, along with proper positioning and repositioning of the person on a regularly-time schedule.^{8,15,17,18} Pressure, shear, and friction are avoided whenever possible.^{2,19-22} Nutrition and continence are monitored to help maintain healthy skin and the correct size wheelchair should be used for the

person. These preventative measures help limit the possibilities of a person developing a pressure ulcer.

Pressure ulcers are defined as "any lesion caused by unrelieved pressure resulting in damage of underlying tissue. Pressure ulcers are usually located over bony prominences and are graded or staged to classify the degree of tissue damage observed." Pressure ulcers are broken down into four stages:

Stage I: Nonblanchable erythema of intact skin, the heralding lesion of skin ulceration. In individuals with darker skin, discoloration of the skin, warmth, edema, induration, or hardness may also be indicators.

Stage II: Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, bliseter, or shallow crater.

Stage III: Full thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

Stage IV: Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures.

Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

Sitting-acquired pressure ulcers are a major concern for the nursing home resident. 1,6,11 Common places for pressure ulcers to occur are at the sacrum or

coccyx, trochanters, and ischial tuberosities. They can lead to pain, discomfort, disfigurement, extended care and rehabilitation time, and even death.²¹

Therefore, maintaining healthy skin is a priority in the prevention of pressure ulcer development.

Cooper et al¹⁶ reported that nearly 40% of the people who develop a pressure ulcer are incontinent. Incontinence is defined as "the involuntary loss of control of the bladder, bowel, or both."^(pS6) With the increased moisture from incontinence, the skin becomes more susceptible to breakdown.²¹ This makes a regular schedule of toileting and proper cleaning following an incident of incontinence just as important as other preventative measures. Incontinence is part of the moisture subscale of the Braden Scale, which helps keep health care professionals aware of any moisture issues.⁶

By implementing prevention protocols, facilities can cut costs and, hopefully, save people from the pain and discomfort of pressure ulcers. If a person does develop a pressure ulcer, the cost of treatment can be staggering. Over \$3 billion a year has been estimated in costs of treatment for people with pressure ulcers. Xakellis et al¹⁷ performed a study on the implementation of a prevention protocol an dfound that it paid for itself. They also found that fewer pressure ulcers occurred during the study, which in turn brought down costs for treatments. This was in direct relation to the prevention protocol. The facility that participated in the study had had no previous prevention protocol established. The prevention protocol that was implemented consisted of policies that were particular to the facility, risk assessment using the Braden Scale, and

treatment of pressure ulcers. Interventions that were used for those found to be at risk of obtaining a pressure ulcer were a regular turning schedule and different types of support sufraces, such as airbeds and wheelchair cushions.

By using a pressure-mapping device in combination with a current prevention program, both the facility and the residents can benefit. The most appropriate pressure-relieving cushion can be chosen for each individual in his or her wheelchair and a better position can be obtained in bed. Pressure-mapping devices can also be used as biofeedback for the individual as well as educational for the family members, individuals, and health care providers. The visual display of the laptop provides viewers with the effects of the weight-shifting techniques, positioning, and pressure-relieving cushions. This makes pressure-mapping devices a valuable addition to any prevention program.

CHAPTER III

METHODOLOGY

Prior to the start of this study, approval for the use of human subjects was obtained from the Institutional Review Board at the University of North Dakota and the LGSNH. A copy of the Human Subjects Review Form and the LGSNH approval letter are located in Appendix A. During the recruitment process and subject selection, each individual was informed that participation was voluntary. The study was explained in detail to each subject and an explanation of the device being used for the study was also given. Interested subjects were asked to sign a consent form. A copy of the consent form is located in Appendix B. To identify any possible health concerns or safety concerns and to gather other vital information, a review of the subject's medical records was done. A copy of the list of items reviewed is located in Appendix C.

Subjects

The subjects in this study were recruited from the LGSNH, Larimore, ND.

They were recruited by the licensed physical therapist (PT) on staff and the primary researcher. It was determined prior to the study that subjects must meet the following inclusion criteria before participation was allowed: equal to or above the age of 62 years, major dependence on a wheelchair for locomotion, nursing home resident, and of sound mind.

There was one exception made for a subject who was 60 years old. She had expressed interest in the research study and wishes to participate. After conferring with the PT on staff and the project advisor, it was felt that she would be a good candidate and should be allowed to participate. She had met the other criteria and had a desire to learn more about pressure reduction. The total number of subjects who met the inclusion criteria and participated in this study was six.

Instrumentation

The Force Sensing Array (FSA) Pressure-Mapping Device (Vista Medical, Ltd., 120 Maryland St., Winnipeg, Manitoba, Canada R3E 1L1, www.vistamedical.org) was used in this study. The device consists of a tactile sensor sheet (mat) connected to a personal computer through an interface board (see Figures 1 and 2).⁴ The FSA mat has 256 available sensors. The software program installed on the laptop computer interprets the information from the mat. The laptop computer produces a visual pressure distribution display of the

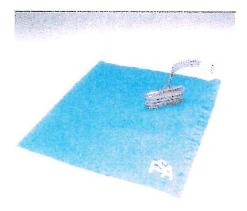






Figure 2. Interface module.

buttocks and legs contacting the upper surface of the wheelchair seat and a pressure distribution map of the area (see Appendix D). The system measures the pressures in mmHG (0-200). See Table 1 for mat description.

Table 1. FSA Mat Description

Mat Material	4-way stretch fabric		
Mat Dimensions	53 cm x 53 cm		
Sensing Area Dimensions	43 cm x 43 cm		
Sensor Number and Type	256 piezo resistive sensors (1024 available on request)		
Sensor Size	24.5 mm x 24.5 mm		
Sensory Arrangement	16 x 16 array		
Mat Thickness	.36 mm		
Sample Rate	3072 sensors per second		
Calibrated Pressure Range	0-200 mmHG		
Accuracy	Variation Coefficient < 10% at manufacturer		
Maximum Allowable Force	0-200 mmHg		

The type of FSA mat used in this study has been tested by independent researchers and has been confirmed to be reliable, repeatable, durable, and accurate. The accuracy is \pm 10% with approximately 8% attributed to creep and approximately 2% attributed to hysteresis with the use of the Type II and Type IV interfaces. Hysteresis is a characteristic of some mechanical and electrical instruments which results in differences in output depending upon whether the

device is being loaded or unloaded. Creep, or stability, describes the change in output readings over time, even though the load stays constant. Hysteresis and creep correction are now integral components of the software.

Three pressure-relieving cushions were used in this study in addition to the present cushion. They were the air, honeycomb, and gel cushions. See Figure 3 in Appendix G for pictures of the cushions. The air cushion was the 17" x19" Roho High Profile Cushion by Roho, Inc., 100 Florida Ave., Belleville, Ill 62222. The honeycomb cushion was the 16" x 18" StimuLite Honeycomb Cushion by Supracor, Inc., 2050 Corporate Court, San Jose, Calif 95131. The gel cushion was the 16" x 18" Jay Cushion by Jay Medical, Ltd., P. O. Box 18656, Boulder, Colo 80308. These cushions were selected because they are commonly prescribed to people with pressure-relief problems.

The wheelchairs that were used by 5 of the 6 subjects were standard nursing home issue. These wheelchairs were the manial collapsible sling back and seat chairs. Three of them did not have leg rests attached. The other wheelchair was motorized and was specifically made to fit the subject. See Figure 4 in Appendix H for pictures of the wheelchairs.

Researcher Training

Prior to beginning this study, the researcher became familiar with the FSA pressure-mapping device by reading the operator manual and using the device on several test subjects as well as himself. Prior to the day of the research study taking place, the researcher tested the device to make sure everything was working properly.

Assessment Procedure

The research study took place at the LGSNH. The licensed physical therapist on staff at the nursing home, the primary researcher, and the researcher's advisor conducted the study. Both the advisor and researcher instructed the subjects and alternated in performing the necessary transfers during the study. The physical therapist on staff provided information concerning each subject throughout the study.

Prior to the pressure mapping, information was recorded from each subject's medical chart. See Appendix C for type of information taken from the medical chart. This information was coded and no names or identifiers were used. Upon completion of the data entry into the computer, testing was performed. Each subject was moved from her wheelchair by her routine transfer technique for placement of the pressure-mapping mat on the seat or current wheelchair cushion. Once the mat had been placed on the wheelchair seat or cushion, the subject was transferred back to the wheelchair and the computer generated the pressure distribution display and map of the buttocks and legs contacting the upper surface of the wheelchair seat or cushion. The data were then saved to a floppy disk.

Three wheelchair cushions used specifically for pressure reduction were also tested for effectiveness of pressure relief for each subject. These were the air, gel, and honeycomb. Each subject was moved from her wheelchair by her routine transfer technique for placement of the cushion and pressure-mapping mat. Each cushion was placed on the wheelchair seat and a 10 cm block of

wood was placed under the feet of 5 subjects. The 10 cm block was used with each cushion to maintain proper seating alignment and pressure distribution of the buttock and leg regions because of the additional height of the cushion and no leg rests on the wheelchair. Each subject was then transferred back to her wheelchair and pressure readings were recorded. The subjects were on each type of cushion for approximately 15 minutes.

The subjects were allowed to see the laptop display of the pressure readings for each cushion. Each subject was also instructed on weight-shifting techniques in their original seating. Subjects were able to observe the effectiveness of their weight shifting by viewing the monitor and seeing the different pressure readings while performing the unweighting techniques. These techniques consisted of leaning to the left, leaning to the right, and leaning forward with elbows on the knees.

Data Analysis

The data gathered from the subjects' medical records and the pressure mapping tests were entered into the SPSS Version 10.0 software program. The descriptive statistics calculated were the mean and standard deviation. A Repeated-Measures Single Factor ANOVA was also calculated to evaluate mean differences among treatment conditions using the data from the subjects in the study. Alpha (α) equals .05 for all tests.

Reporting of Results

Upon completion of this study, a copy of the results of this scholarly project was given to both the University of North Dakota Department of Physical

Therapy and the University of North Dakota Library of the Health Sciences. This study was completed to fulfill the requirements of the University of North Dakota School Department of Physical Therapy.

CHAPTER IV

RESULTS

The results from this study consisted of pressure measurements from the FSA pressure-mapping device and demographics. The data obtained from 6 subjects' assessments were analyzed using descriptive statistics. The results to be reported are the subject profile and descriptive statistics followed by the analysis of each research question.

A total of 6 female subjects participated in this study with ages ranging from 60 to 88 years. The mean calculated age was 78.8 years with a standard deviation of 10.9. All subjects participated in testing of their own cushion provided by the LGSNH and the air, gel, and honeycomb cushions provided by the researcher. This was followed by education on weight-shfiting techniques and proper positioning while seated in the wheelchair. No subjects were excluded and all data were used except that Subject 3's air cushion average pressure was excluded and maximum pressure was adjusted. A small wrinkle in the pressure-mapping mat gave some incorrect readings at that location. Subject 2's original cushion and no cushion maximum pressures were also adjusted. This was due to a corner of the pressure-mapping mat being pinched.

Five of the 6 subjects had their own manual wheelchairs they used for locomotion and sitting. One subject used a motorized wheelchair for locomotion.

This wheelchair was made specifically to fit her with a pressure-relieving wheelchair cushion (StimuLite). Three subjects used their feet for propulsion and had the leg rests removed from their chairs. The height of the wheelchair seat allowed for their feet to contact the floor. Two subjects propelled themselves with the use of their hands and arms or had someone else push them in their wheelchairs with leg rests attached. See Table 2 for further subject profile and descriptive statistics.

Table 2. Subjects' Profile and Descriptive Statistics

	Mean	Standard Deviation	Minimum	Maximum
Age	78.8	10.87	60	88
Height (inches)	62.0	1.90	59	65
Weight (pounds)	157.7	19.60	131	180
Braden Score	17.0	2.50	14	21

Research Questions

Research Question #1: Are the wheelchair cushions provided for the LGSNH residents adequate for pressure relief?

All of the subjects in this study spent 8 or more hours each day in their wheelchair. Five of the 6 subjects who participated were using a cushion prior to this study. One subject was using no cushion. Four subjects were using a monitor with a 3/4" foam cushion provided by LGSNH and one was using a honeycomb cushion that she purchased. All of the subjects' average pressures

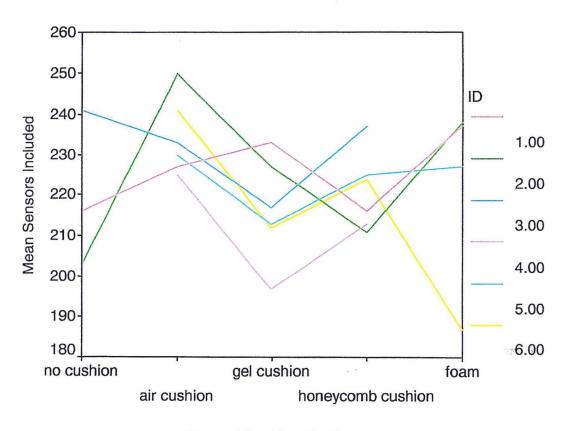
were below the recommended pressures with their original cushions as well as the one subject without a cushion. See Table 3 for results. However, 5 of the 6 subjects did have specific areas that exceeded the maximum recommended pressure amounts. The maximum-recorded pressures were located at the sacrum for Subjects 1 and 3 and an ischial tuberosity for Subjects 2, 4, and 6. These subjects had good distribution of pressure, so were not considered to be at high risk. Five of the 6 subjects exceeded 200 sensors out of the 256 available sensors for distribution of pressure. One subject was at 187 sensors. Four of the 6 subjects had Braden scores of 15 to 18 for a low risk of pressure sore development, while one scored a 14 and the other a 21. See Table 3 for results. See Table 4 in Appendix F for complete breakdown of Braden Scale scores for each subject.

Table 3. Data Results of Original Cushion Being Used

Subject	Average Pressure, mmHg	Max Pressure, mmHg	Sensors	Braden Score	Hours in Chair
1	57.6	145	237	18	10+
2	42.6	134	236	21	12+
3	48.8	133	241	15	10+
4	28.1	130	213	16	12+
5	27.5	95	227	18	8+
6	48.0	125	187	14	12+

Research Question #2: What type of pressure-relieving wheelchair cushion provides the best pressure relief for elderly nursing home residents, the air, gel, or honeycomb cushion?

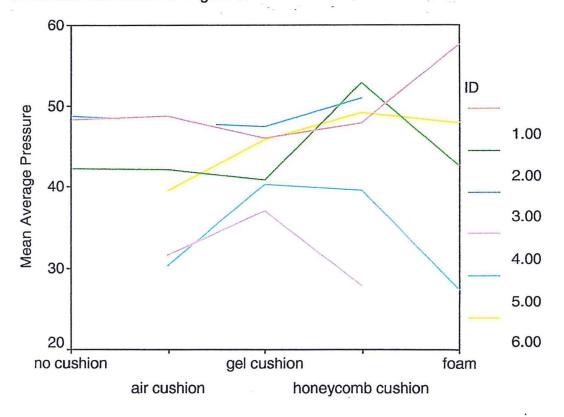
The mean number of pressure sensors registering for the air cushion was 234 ± 10 , the foam cushion was 222 ± 24 , the honeycomb cushion was 221 ± 10 , and the gel cushion was 217 ± 13 . A Repeated Measures Single Factor ANOVA test was performed on the data. The results for the number of sensors being used demonstrated no significant difference in sensor numbers between cushion types (F(4, 15) = 1.602, p = .225, power = .377). Each individual responded differently to the cushions and the number of sensors used demonstrates this difference. See Figure 5 for individual results.



Type of Cushion/Seating

Figure 5. Mean pressure sensors registering.

The mean average pressure for the air cushion was 38.58 ± 7.61 , the foam cushion was 43.93 ± 12.59 , the honeycomb cushion was 44.82 ± 7.37 , the gel cushion was 42.95 ± 4.15 , and no cushion was 46.50 ± 3.64 . A Repeated Measures Single Factor ANOVA test was performed on the data. The results for the average pressure were no significant difference between cushion types (F(4, 14) = .772, p = .561, power = .190). Each subject responded differently to each wheelchair cushion. The average pressures for each subject on each wheelchair are shown in Figure 6.

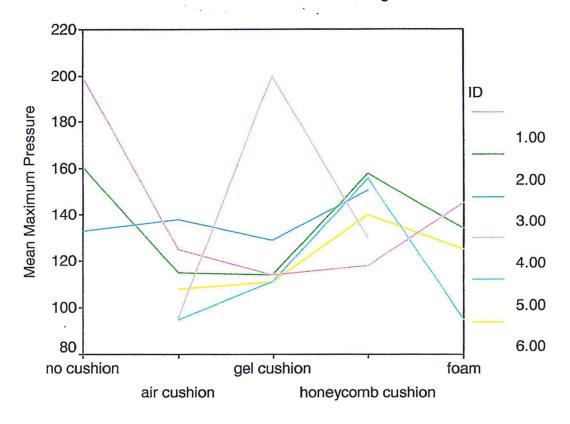


Type of Cushion/Seating

Figure 6. Mean average pressure.

The mean maximum pressure for the air cushion was 112.83 ± 16.80 , the foam cushion was 124.75 ± 21.45 , the honeycomb cushion was 142.17 ± 15.86 ,

the gel cushion was 129.83 ± 35.03 , and no cushion was 164.67 ± 33.65 . A Repeated Measures Single Factor ANOVA test was performed on the data. The results for the maximum pressure were no signflicant difference in maximum pressure between cushion types (F(4, 15) = 1.837, p = .174, power = .429). Each individual responded differently to each cushion. The maximum pressures for each individual on each cushion are shown in Figure 7.



Type of Cushion/Seating

Figure 7. Mean maximum pressure.

Research Question #3: With proper instructions and education, can the nursing home residents decrease pressure by proper positioning and weight shifting?

Following education and instruction on proper positioning in a wheelchair, all of the subjects were able to demonstrate proper positioning in a wheelchair at

that time and approximately an hour later. Subjects were also able to demonstrate the effective weight-shifting techniques following education and instruction of the three different weight shifting techniques following education and instruction of the three different weight shifting techniques: leaning to the left, leaning to the right, leaning forward with elbows on knees. This was accomplished by using the pressure-mapping device as a biofeedback tool. The subjects were able to view the graphics display on the monitor of the laptop computer and see the changes in prsesure evidenced by the change in colors and numbers on the display. Each subject stated that it was beneficial to see the display and the real-time measurements.

CHAPTER V

DISCUSSION

Pressure sores are one of the most common problems for elderly nursing home residents who spend multiple hours in a wheelchair. Several factors that contribute to the development of pressure sores were mentioned earlier in this study. Some of them are type of wheelchair, positioning, pressure, shear, friction, malnutrition, and incontinence.

Pressure sores will often occur at the bony prominences of the buttocks. To help prevent the development of pressure sores while seated in a wheelchair, proper positioning, weight-shifting techniques, and pressure-relieving wheelchair cushions are used. Wheelchair cushions are designed to help distribute the pressure of the buttock and leg regions over a wider area reducing the average pressure and lowering the maximum pressure points. This will help reduce the chance of developing a pressure sore. Therefore, the use of a pressure-mapping device to measure the pressure distribution of the buttock and leg regions on a wheelchair cushion is a valuable tool in choosing the most adequate cushion for a particular individual.

The data collected from the subjects (Appendix D) revealed that the original cushions that the individuals were using met the average pressure recommendations (60 - 80 mmHg) as well as the number of sensors registering

(> 200) for the distribution of pressure. However, only one subject was below the recommended maximum pressure of 120 mmHg. This would suggest that the subjects might be at risk for the development of pressure sores if they do not have adequate pressure relief in these areas. Five of the 6 subjects were tested in wheelchairs that were issued by the nursing home. This can make a difference in pressure readings as well, especially if the wheelchair does not fit the person properly. The type of propulsion the subject uses for the wheelchair can also have an effect on the amount of pressure on the buttock and leg regions. The height of a cushion can affect the ability to propel a wheelchair depending on the height of the wheelchair. Some of the subjects used their feet and legs for propulsion, while others used their hands or were pushed. One subject used a motorized wheelchair. Comfort is also an issue when choosing a wheelchair. Each subject stated that the wheelchair she was using was comfortable.

The results from a statistical standpoint indicate that there is no significant difference between the air, gel, honeycomb, and subjects' original cushions in the mean number of pressure sensors registering, mean average pressure, or the mean maximum pressure. Statistical power was also low for each test, which could be due to the small sample size and the short duration of the study. Power was close to an acceptable level of .429 for maximum pressure between cushions, yet there was no significant difference in maximum pressures between the cushions. The statistics do reveal that the subjects responded differently to

the different cushions. Viewing Figures 1, 2, and 3 will verify this. This is due to the different body shapes, contours, heights, and weights of each individual.

Although not statistically significant, there was a pattern of the data showing an order of the cusions that provided better pressure relief. Overall, the air cushion ranked first followed by the gel cushion and then they honeycomb cushion according to the mean totals of pressure snesors registering, average pressure, and maximum pressure. When each individual's data were examined, the order of which cushion was better changed. Again, this was due to how each individual responded differently to the different cushions. For example, 3 of the 6 subjects had lower maximum pressures with the air cushion, while the other 3 subjects had lower maximim pressures with the gel cushion. The second ranked cushion was split evenly with 2 subjects for each cushion. For the third ranked cushion, 4 had the honeycomb cushion and one subject each for the air and gel cushions. The data supports the need for the use of a pressure-mapping device in order to find the better cushion for individuals. As mentioned earlier, each individual responded differently to the different cushions.

The use of the pressure-mapping device for subject education was also beneficial. The subjects were able to see the effects of proper positioning and weight-shifting techniques by viewing the monitor and seeing the graphic display changes of the pressure readings in real-time. This gave them the visual feedback needed in order to have a better understanding of what was happening with the pressure and why one movement was better than the other. Each

subject responded positively to the feedback. The graphic displays on the monitor acted as reinforcement for the instructions given to the subjects.

Three limitations were noted in this study. One was the fact that only one cushion was brand new and the other two were not. This factor may affect the validity of the study because the extent of wear or deterioration of the two cushions was not known. This could be avoided by choosing cushions that are all new and not previously used. This would eliminate any questions concerning the validity fo the results from the cushions. However, the aim of this study was to show the usefulness of a pressure-mapping device in choosing the correct cushion for individuals.

The second limitation was the length of time used in taking the pressure measurements. Each subject was measured for approximately 15 minutes on each cushion. This could have been improved by having the subjects use a cushion for one day while taking pressure readings each hour of that day. In order to get appropriate readings, the height of the wheelchair seats or leg rests would have to be adjusted to allow for the height of the cushion.

The third limitation was the number of subjects who participated in the study. This was represented by the low power statistics. Obtaining a larger sample to test could change this. It should contain at least 10 subjects or more. The subjects should be from all populations in a nursing home not just those of sound mind. By having a larger sample size, the data results could possibly have statistical significance between groups of subjects and cushions and have greater power. Error and results by chance tend to decrease while reliability may

increase. With a larger sample size, there may also be different sized people who need a different size cushion. This problem could be avoided by having different sizes available in each type of cushion.

CHAPTER VI

CONCLUSION

This study demonstrates the benefits of using a pressure-mapping device and illustrates a research design used for the comparison of three pressure-relieving wheelchair cushions for short-term pressure relief. The results of this study would be better represented with more subjects and a long-term performance of the cushions as suggested in the limitations and recommendations. With the current data results, the air cushion distributed pressure from the buttock and leg regions best, following by the gel cushion and then the honeycomb cushion. All of the subjects' average pressure were below the recommended pressures with their original cushions provided by LGSNH. Five of the 6 subjects did have specific areas that exceeded the maximum recommended pressure amounts. However, these subjects also had good distribution of pressure with their original cushion, thus were not considered to be at high risk for pressure sore development.

Further research is needed in the nursing home setting. The literature review found that there were few studies that pertained to the use of a pressure-mapping device, elderly nursing home residents, pressure-relief cushions, and a training tool for teaching appropriate pressure-relief techniques.



University of North Dakota Human Subjects Review Form

Please Note: The policies and procedures of the University of North Dakota apply to all activities involving the use of Human Subjects performed by faculty, staff and students conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedure governing the use of human subjects. When preparing your Human Subjects Review Form, use the attached "IRB Checklist".

Please provide the information requested below: Principal Investigator: Brian Rud Telephone: (701) 777-9604 Address: 3904 University Ave. #107 Grand Forks, ND 58203 E-mail address: barud1@yahoo.com School/College: UND Department: Physical Therapy Student Adviser (if applicable): Meridee Danks (701) 777-2831 or Telephone: (701) 777- 3861 Address: P.O. Box 9037 Grand Forks, ND 58202-9037 E-mail address: mgreen@medicine.nodak.edu School/College: UND Department: Physical Therapy Project Title: Sitting Pressure-Mapping of the Buttocks Region of Elderly People Who Use Wheelchairs for Locomotion Proposed Project Dates: Beginning Date: August 26, 2002 Completion Date: May 2, 2003 Funding agencies supporting this research: (A copy of the funding proposal for each agency identified above MUST be attached to the proposal when submitted.) YES or x NO Does the Principal Investigator or any researcher associated with this project have a financial interest in the results of this project? If yes, please submit on a separate piece of paper an additional explanation of the financial interest (other than receipt of a grant) If your project has been or will be submitted to another Institutional Review Board (s), Please list those boards below along with the status of each proposal. Date Submitted: Status: Approved Pending Date Submitted: Status: Approved Pending Type of Project: Please Check Yes or No to the following. x YES or NO New Project YES or X NO Dissertation/Thesis x YES or NO Student Research Project YES or x NO Continuation/Renewal YES or x NO Protocol Change for previously approved project (resubmit "Human Subjects Review Proposal" with changes bolded or highlighted and signed) Larimore Good Samaritan Nursing Home Cooperating Institution: x YES or NO Will any institution of agency personnel assist in the Proposed Project? Copies of letters indicating the willingness of the institution/agency to cooperate in the study and an understanding of the study MUST be attached. Letters must include the name and title of the

individual signing the letter and, if possible, should be printed on letterhead.

Subject Classification: This study will involve subjects who are in the following special populations: Check all that app	ıly.
Minors (<18 years)	
Prisoners	
Pregnant Women/Fetuses	
Persons with impaired ability to understand their involvement and/or consequences of participation in this rese	arch
UND Students	
Other	
section on the Office of Research and Program Development website. This study will involve: Check all that apply.	
New Drugs (IND)	
Non-approved Use of Drug(s)	
Recombinant DNA	
Fetal Tissue	
Stem Cells	
Other (Discarded tissue, fluids, blood, etc.)	
None of the above will be involved in this study	

I. Project Overview

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as minors, prisoners, pregnant women/fetuses).

Elderly people who spend multiple hours in a wheelchair are prone to skin breakdown of the buttocks and legs. Pressure relief of these areas is needed in order to prevent skin breakdown. Pressure relief can be achieved by the use of wheelchair cushions, weight shifting and positioning. In combination with a newer method of pressure mapping, the best type of pressure relief can be found for each individual. The Force Sensitive Applications© (FSA) pressure-mapping device consists of a tactile sensor sheet connected to a personal computer through an interface board. The personal computer produces a visual pressure distribution display of the buttocks and legs contacting the upper surface of the wheelchair seat and a pressure distribution map of the area. The data displayed by the computer can be used by the therapist to choose the most appropriate type of intervention and show the effectiveness of that intervention. This study will use the pressure-mapping device to find the best intervention for pressure relief in sitting for elderly people in a long term care facility who are of sound mind and have a major dependence on a wheelchair for locomotion.

II. Protocol Description

Please provide a succinct description of the procedures to be used by addressing the instructions under each of the following categories. Individuals conducting clinical research please refer to the "Guidelines for Clinical-Research Protocols" on the Office of Research and Program Development website.

1. Subject Selection.

- a) Describe recruitment procedures (i.e., how will subjects be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects. The subjects will be recruited by the licensed physical therapist on staff (Schawnn Decker, MPT) and the primary investigator and student physical therapist (Brian Rud) doing the research. The recruitment process will consist of asking subjects if they would like to participate in a research study. The research will take place at the nursing home and recruitment will continue until the number of subjects needed has been met.
- b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the "Subject Classification" section above.
 The subjects will be chosen because of their age, sound mind (able to give their own consent), and major dependence on a wheelchair for locomotion.
- Describe your exclusionary criteria and provide a rationale for excluding subject categories.
 People who are not of sound mind will be excluded because they would be unable to understand instructions and provide their own consent.
- d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects. Up to 10 subjects (both male and female) equal to or above the age of 62 will be recruited from the Larimore Good Samaritan Nursing Home. The number of subjects chosen is the maximum number of subjects that fit the inclusion criteria.
- e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.

NA

2. Description of Methodology.

- a) Describe the procedures used to obtain informed consent.
 - The subjects will be recruited by the licensed physical therapist on staff and the student physical therapist doing the research. Each subject will be given an informed consent form to read and sign. It will briefly describe the study. Once the consent form has been signed, each subject will be asked to participate voluntarily for approximately 30 minutes to one hour.
- b) Describe where the research will be conducted.
 - The research will take place at the Larimore Good Samaritan Nursing Home in the Physical Therapy Department.
- c) Indicate who will carry out the research procedures. Schwann Decker, MPT and advisor Meridee Danks, MPT, instructors of the Physical Therapy Department at the University of North Dakota and graduate student Brian Rud, SPT, will conduct the research. Schwann Decker, MPT works regularly at the nursing home. Meridee Danks, MPT and Brian Rud, SPT have been trained in the use of the FSA pressure-mapping device.
- d) Briefly describe the procedures and techniques to be used and the time required to complete them.

 Prior to the pressure mapping, the subjects' age, height, weight and any other pertinent information (average time in wheelchair, incidence of pressure sores, etc.) to the study will be recorded from their medical chart. Each subject will then be moved from the wheelchair by a routine transfer technique for placement of the pressure-mapping pad on the seat or current wheelchair cushion. Once the pad has been placed on the wheelchair seat or cushion, the subject will be transferred back to the wheelchair and the computer will record pressure readings. Three wheelchair cushions used for pressure reduction will be compared for effectiveness of pressure relief. The computer will record pressure readings for each cushion. The subject will also be instructed on techniques to unweight himself or herself and pressure readings will be recorded by the computer and compared for effectiveness of pressure relief. Once all the readings have been recorded, the pressure-mapping pad will be removed. The subject will be free to ask questions at any time.
- e) Describe audio/visual procedures and proper disposal of tapes.
- f) Describe the qualifications of the individuals conducting all procedures used in the study. Schwann Decker, MPT works regularly at the nursing home. Meridee Danks, MPT and Brian Rud, SPT have been trained in the use of the FSA pressure-mapping device.
- g) Describe compensation procedures (payment or class credit, etc.)
 NA

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

3. Risk Identification.

- a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.
 - The risks involved in this study are minimal and are only those associated with routine patient care.
- b) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).Subjects will have the research explained to them and will be informed that participation is voluntary and may quit at any time. Use of a clean disposable plastic sleeve for each subject will control any contamination. This sleeve is designed to cover the pad and not interfere with the readings.
- c) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and, if so, what the justification is for having that link.
 - The data recorded for each subject will be confidential. Names will be number coded and will not be used in any reports of the results of this study.

4. Subject Protection

- a) Describe procedures you will implement to protect confidentiality (such as coding subject data, removing identifying information, reporting data in aggregate form, etc.).
 - The subjects' names will be number coded and will not be used in any reports of the results of this study.
- b) Indicate that the subject will be provided with a copy of the consent form and how this will be done. Subjects will have the research explained to them and will be informed that participation is voluntary and that they may quit at any time. Each subject will be asked to sign an informed consent form and upon agreement of the terms will be included in the study. Each subject will be given a copy of his or her consent form for future reference. The primary researchers and advisors names and telephone numbers will be given to address any questions.
- c) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.

Describe: a) the storage location of research data (separate from consent forms and subject personal data)

- b) who will have access to the data
- c) how the data will be destroyed
- d) the storage location of consent forms and personal data (separate from research data)

- University of North Dakota Human Subjects Review Form, Page 4 department. Only the primary investigator and the advisor will have access to the data and consent forms. The data and consent forms will be stored for a period of 3 years and then will be shredded and/or electronically erased.
- d) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma etc.). In the event that this research activity results in an injury, medical personnel will be notified immediately.
- e) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.
 - In the event that this research activity results in an injury, medical personnel will be notified immediately. The subjects' third party payer if any, must provide payment for any treatment of injury. There will be no payment for participation in this study.

III. Benefits of the Study

Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). Please note: payment is not a benefit and should be listed in the Protocol Description section under Methodology. The primary aim of this study is to identify elderly subjects in wheelchairs that have pressure relief problems of the buttocks and legs regions and to help relieve that pressure. This will help prevent sitting acquired pressure sores from occurring and discomfort. The benefits of this study will be several. The results of this study can assist physical therapists in choosing the best cushion available for patients. Subjects will benefit from exposure to the research process and the knowledge that they are helping improve the field of physical therapy. The subjects will also benefit from the knowledge of how to help prevent their own pressure sores. Facilities can also benefit from the study. Pressure sores can be a staggering expense for facilities. Treatment of pressure sores is very time consuming and difficult as well as expensive. With better pressure relief for subjects, sitting acquired pressure sores can be avoided and so can the expense of treatments for them.

IV. Consent Form

A copy of the Consent Form must be attached to this proposal. If no Consent Form is to be used, document the procedures to be used to protect human subjects. Refer to the ORPD website for further information regarding Consent Form Regulations.

Please note: Regulations require that all Consent Forms, and all pages of the Consent Forms, be kept for a minimum of 3 years after the completion of the study, even if subject does not continue participation. The Consent Form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. It is recommended that the Consent Form be written in the third person (please see the examples on the ORPD website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp. The consent form must include the following elements:

- a) An introduction of the principal investigator
- b) An explanation of the purposes of the research.
- c) The expected duration of subject participation.
- d) A brief summary of the project procedures.
- e) A description of the benefits to the subject/others anticipated from this study
- f) A paragraph describing any reasonably foreseeable risks or discomforts to the subject.
- g) Disclosure of any alternative procedures/treatments that are advantageous to the subject
- h) A description of how confidentiality of subjects and data will be maintained. Indicate that the data and consent forms will be stored separately for at least three years following the completion of the study. Indicate where, in general, the data and consent documents will be stored and who has access. Indicate how you will dispose of the data. Be sure to list any mandatory reporting requirements that may require breaking confidentiality.
- i) An explanation of compensation/medical treatment available if injury occurs
- j) The names, telephone numbers and addresses of two individuals to contact for information (generally the student and student adviser). This information should be included in the following statement: "If you have questions about the research, please call (insert Principal Investigator's name) at (insert phone number of Principal Investigator)or (insert Adviser's name) at (insert Adviser's phone number). If you have any other questions or concerns, please call the Office of Research and Program Development at 777-4279."
- k) If applicable: an explanation of who to contact in the event of a research-related injury to the subject.
- l) If applicable: an explanation of financial interest must be included.
- m) RE: Participation in the study:

they can discontinue participation.

- 3) An explanation of circumstances which may result in the termination of a subject's participation in the study.
- 4) A description of any anticipated costs to the subject.
- 5) A statement indicating whether the subject will be informed of the findings of the study.
- 6) A statement indicating that the subject will receive a copy of the Consent Form.

By signing below you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Requirements for submitting proposals:

Additional information can be found at Office of Research and Program Development website at www.und.nodak.edu/dept/orpd

Original Proposals and all attachments should be submitted to: Office of Research and Program Development (ORPD), P. O. Box 7134, Grand Forks, ND 58202-7134, or drop off at Room 105, Twamley Hall.

The criteria for determining what category your proposal will be reviewed as is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require Full Board review, you will need to provide additional copies. Further information can be found on the ORPD website regarding required copies and IRB review categories or you may call the ORPD office.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 7 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 7 copies of the company's protocol must be provided.

Please Note: Student Researchers must complete the attached "Student Consent to Release of Educational Record".

Federal regulations require that key personnel involved in human subject research complete educational training. The UND IRB has chosen an online educational course, which can be found at www.miami.edu/citireg, for this training. The online Educational Modules must be completed before approval is granted for a proposal. In addition, Principal Investigators must provide a list of the key personnel involved in the project to ORPD, so the office can maintain records of those individuals that have completed training.

Revised 7/27/2001

REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW

University of North Dakota Institutional Review Board

Date:	Augus	26, 2002		Project Number:	IRB-200208-030
Name:	Brian	Rud		Department/College:	Physical Therapy
Project	Title:	Sitting Pressure-Mapping of	f the Buttocks R	egion of Elderly People Wh	no Use Wheelchairs for
		Locomotion			
on	Aug	erenced project was reviewed gust 28, 2002 pproved. Expedited Review	and	d member for the Universit the following action was to	y's Institutional Review Board aken:
	-	eduled review must be before		August 27, 2003	
Þ	()	pies of the attached conse ptaining consent for this st	nt form dated	August 28, 20	02 must be used in
BM P	roject a	pproved. Exempt Review Ca	ategory No.		
IT 🔯	his app	roval is valid until		as long as	approved procedures are
fo		No periodic review schedule		ted in the Remarks Section	
		pies of the attached conse taining consent for this stu			must be used in
☐ ap fo	pproval or further roject a emarks RKS: A t	This study may NOT be start information.) approval deferred. This study is Section for further information. Any adverse occurrences in the IRB Chairperson or ORF any changes in protocol or mented. You must submit a Subjects Review Form, with Development for review and	arted UNTIL fina ly may not be s on.) the course of D. Consent Forms a memo with a of the appropriat d approval.	tarted until final IRB apports the research project musts s must receive IRB appro- copy of the Consent Form the signatures, to the Office	n and a revised Human e of Research and Program
PLEAS	SE NOT	E: Requested revisions for MUST be highlighted.	or student prop	osals MUST include advi	ser's signature. All revisions
		Education Requirements Con	npleted. (Projec	t cannot be started until IRB	education requirements are met.)
CC: Me	eridee D	anks, Adviser	Signature of D	esignated IRB Member	ay 28, 2007
				onal Review Board	1

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special

Brian Rud 3904 University Ave. #107 Grand Forks, ND 58203 Phone: 701-777-9604

Larimore Good Samaritan Nursing Home Attn: Karen Boulden PO Box 637 Larimore, ND 58251

Dear Ms. Karen Boulden:

My name is Brian Rud and I am a Graduate student in the Physical Therapy program at the University of North Dakota. We spoke on the phone Wednesday July 31, 2003 concerning my graduate project. It is pressure mapping of the buttocks and hip regions for elderly people who use wheelchairs for locomotion. I would like to be able to do my research at your facility with the assistance of Schawnn Decker, MPT. She is one of my instructors and I have worked with her previously at your facility. I am completing my Institutional Review Board (IRB) application and will need a letter of approval to conduct my research study at your facility.

Following is a brief explanation of my project.

People who spend multiple hours in a wheelchair are prone to skin breakdown of the buttocks and hips. Pressure relief of these areas is needed in order to prevent skin breakdown. There are many methods of pressure relief and in combination with a newer method of pressure mapping, the best type of pressure relief can be found for each individual.

The pressure-mapping device, which will be used in the study, consists of a tactile sensor sheet connected to a personal computer through an interface board. The personal computer produces a visual pressure distribution display of the buttocks and hips contacting the upper surface of the wheelchair seat and a pressure distribution map of the area. The data displayed by the computer can be used by the therapist to choose the most appropriate type of intervention and show the effectiveness of that intervention. This study will use the pressure-mapping device to find the best intervention for pressure relief for elderly people who are of sound mind and dependent on a wheelchair for locomotion.

Up to 10 subjects (both male and female) equal to or above the age of 62 will be recruited. The subjects will be chosen because of their age, sound mind (able to give their own consent), and major dependence on a wheelchair for locomotion. People who are not of sound mind will be excluded because they would be unable to understand instructions, benefits of the study, or provide their own consent. The research will take

place at the nursing home and each subject will be asked to participate voluntarily for approximately 30 minutes to one hour. The subjects will be recruited by the licensed physical therapist on staff (Schawnn Decker, MPT) and the student physical therapist (Brian Rud) doing the research. My project advisor, Meridee Danks, MPT will also be assisting in the research. This is a research project that will use a pressure-mapping device and pressure relief interventions that have been used in previous studies on younger individuals and have been found to be valid. Long-term results are not part of this study.

Prior to the pressure mapping, the subjects age, height and weight will be recorded from their medical chart. Each subject will then be moved from the wheelchair by a routine transfer technique for placement of the pressure-mapping pad on the seat. The subjects will either do an independent (by themselves) transfer or an assisted (help of the physical therapists) transfer; whichever is easier for the subject. Once the pad has been placed on the wheelchair seat, the subject will be transferred back to the wheelchair and pressure readings will be recorded. The subject will then be instructed on techniques to unweight himself or herself and readings will be recorded. Several wheelchair cushions will also be compared for effectiveness of pressure relief. Once the readings have been recorded, the pressure-mapping pad will be removed and the subject will be free to ask any questions.

The risks involved in this study are minimal and are only those associated with routine patient care. Subjects will have the research explained to them and will be informed that participation is voluntary and that they may quit at any time. Each subject will be asked to sign an informed consent form and then will be asked to participate in the study. Use of a clean disposable plastic sleeve for each subject will control contamination or infection. This sleeve is designed to cover the pad and not interfere with the readings. The data recorded for each subject will be confidential and names will not be used in any reports of the results of this study. The results of this study can be shared with the nursing home staff.

The primary aim of this study is to help subjects relieve pressure on the buttocks and hips region. This will help prevent discomfort and pressure sores from occurring. The benefits of this study will be several. The results of this study can assist physical therapists in choosing the best cushion available for patients. Patients will also benefit from exposure to the research process and the knowledge that they are helping improve the field of physical therapy. The subjects will also benefit from the knowledge of how to help prevent their own pressure sores. Facilities will also benefit from the study. Pressure sores can be a staggering expense for facilities. Treatment of pressure sores is very time consuming and difficult as well as expensive. With better pressure relief for subjects, pressure sores can be avoided and so can the expense of treatments for them.

In the event that this research activity results in an injury, the subjects' third party payer if any, must provide payment for any treatment of injury. There will be no payment for participation in this study.

I hope this gives you an idea of what my research project is about. The date the study will take place is yet to be determined, but anticipate completion between the dates of August 12 and December 20, 2002. As per federal law, UND IRB must approve this project. The project will not be started until approval has been received from both Larimore GSNH and UND.

At the bottom of this letter I am placing a signature line for you and approval and disapproval lines for your choice in checking. I am including two copies of this letter, one for you to keep at the facility and one to return to me, which I will keep.

If you have any questions, please feel free to contact me at my home number or Schawnn Decker or Meridee Danks at the address and phone number listed below. You may mail the approval to my home address listed above. Thank you for you assistance and prompt reply.

The address at the university is as follows: UND Physical Therapy Department PO Box 9037 Grand Forks, ND 58202 Phone: 701-777-2831

Sincerely,

Brian Rud, SPT

_X	Permission to conduct the stu- Samaritan Nursing Home is	2 1 11 0	he Larimore Good			
	Permission to conduct the stu Samaritan Nursing Home wi	, , , , , ,				
	Permission to conduct the study of pressure mapping at the Larimore C Samaritan Nursing Home is denied for the following reason(s):					
0	Signature Karen Boulden	Administrator Title	08/06/02 Date			

APPENDIX B

APPROVED BY

AUG 28 2002

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INFORMATION AND CONSENT FORM

University of North Dakot Institutional Review Boar

TITLE: Sitting Pressure-Mapping of the Buttocks Region of Elderly People Who Use Wheelchairs for Locomotion

You are invited to participate in a study conducted by Brian Rud, SPT, Schawnn Decker, MPT and Meridee Danks, MPT from the Physical Therapy Department at the University of North Dakota. The purpose of this study is to compare the effectiveness of different wheelchair cushions, weight shifting techniques and positioning on relieving pressure of the buttocks and legs regions. This will be accomplished by using a pressure-mapping device to record pressure readings. The pressure-mapping device consists of a sensor pad connected to a personal computer. The personal computer produces a visual pressure distribution display of the buttocks and legs contacting the upper surface of the wheelchair seat and a pressure distribution map of the area. Participation in the study will be approximately 30 minutes to one hour.

Prior to the pressure mapping, your age, height, weight and any other pertinent information to the study will be recorded from your medical chart. You will then be moved from the wheelchair by a routine transfer technique for placement of the pressure-mapping pad on the seat or current wheelchair cushion. Once the pad has been placed on the wheelchair seat or cushion, you will be transferred back to the wheelchair and the computer will record pressure readings. Three different wheelchair cushions will be compared for effectiveness of pressure relief. The computer will record pressure readings for each cushion. You will also be instructed on techniques to unweight yourself and pressure readings will be recorded by the computer and compared for effectiveness of pressure relief. Once all the readings have been recorded, the pressure-mapping pad will be removed. You will be free to ask questions at any time.

The risks involved in this study are minimal and are only those associated with routine patient care. You may quit the study at any time, as it is strictly voluntary. Your decision whether or not to participate will not prejudice your future relationship with the Larimore Good Samaritan Nursing Home, The Physical Therapy Department or the University of North Dakota. Use of a clean disposable plastic bag for the pad will control any contamination. The data recorded will be confidential and names will not be used in any reports. In the event that this research activity results in an injury, medical personnel will be notified immediately. You and your third party payer, if any must provide the payment for any treatment of injury. There will be no payment for participation in this study.

Any information that is obtained in connection with this study and that can be identified with your name will remain confidential and will be disclosed only with

your permission. The data from the study will be stored in a locked confidential file located in the Physical Therapy Department of the UND School of Medicine and Health Sciences. Consent forms will be stored in a separate locked confidential file in the department. Only the primary investigator and the advisor will have access to the data and consent forms. The data and consent forms will be stored for a period of 3 years and then will be shredded and/or electronically erased.

The benefits of this study will be several. The results of this study can assist physical therapists in choosing the best cushion available for elderly people. You will also benefit from exposure to the research process and the knowledge that you are helping improve the field of physical therapy. You will also benefit from the knowledge of how to help prevent your own pressure sores. Facilities can also benefit from this study. The treatment of pressure sores can be a staggering expense for facilities. With better pressure relief for people, sitting acquired pressure sores can be avoided and so can the expense of treatments for them.

The investigator involved is available to answer any questions you might have concerning this study now or in the future. Questions may be asked by contacting Brian at (701) 777-9604, Meridee and Schawnn at (701) 777-2831 or the UND Office of Research and Program Development at (701) 777-4279. A copy of this consent form is available to all participants in this study.

I have read all of the above, all my questions have been answered, and I willingly agree to participate in this study explained to me by the investigators.

Participant's Signature	Date
Witness	Date

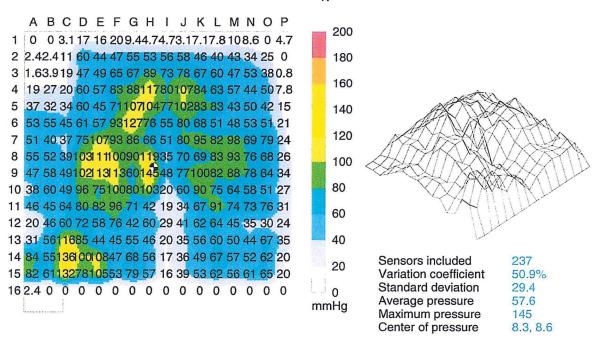


Medical Information

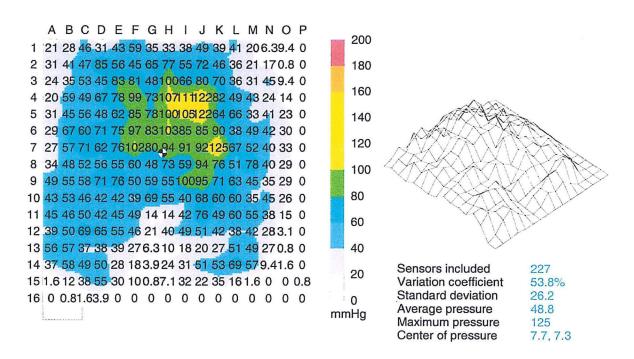
Name Code:
Sex:
Facility:
Date of Birth:
Height:
Weight:
Original Cushion:
Diagnosis:
Hours in Chair:
History of Skin Breakdown:
Posture:
Propulsion:
Braden Score:





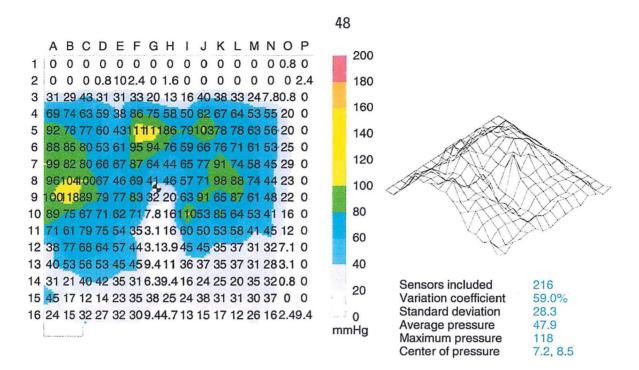


Original cushion. Micro Tech chair sensor cushion, 3/4" foam.

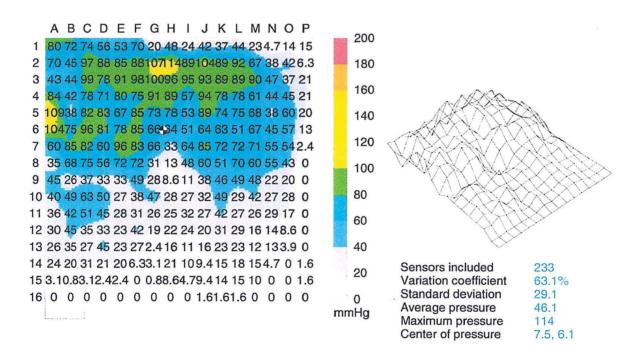


Air cushion.

Subject One



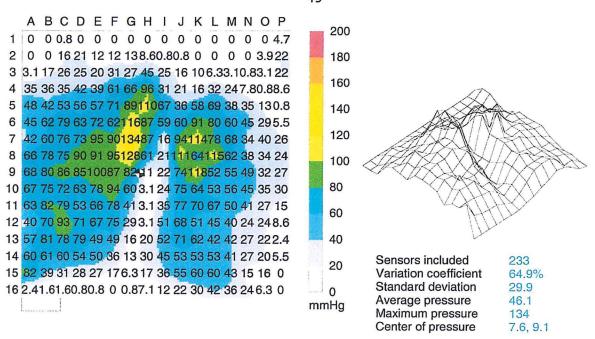
Honeycomb cushion.



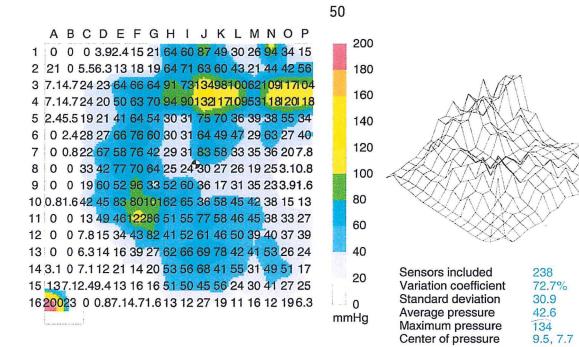
Gel cushion.

Subject One continued

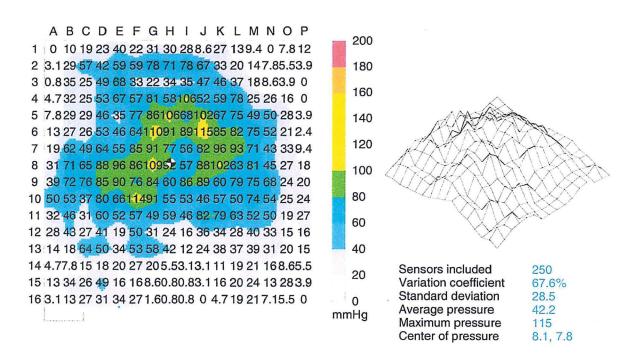




No cushion and feet on the floor.

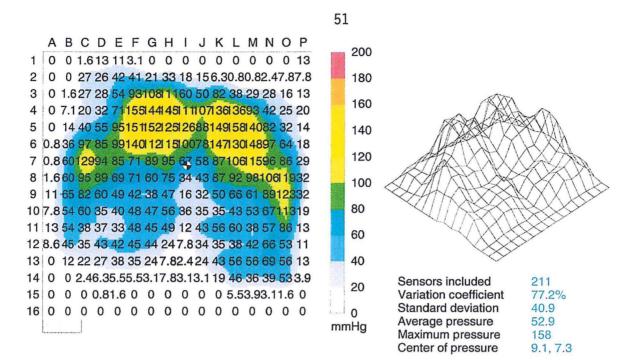


Original pad. Val Med MW5000, 3/4" foam.

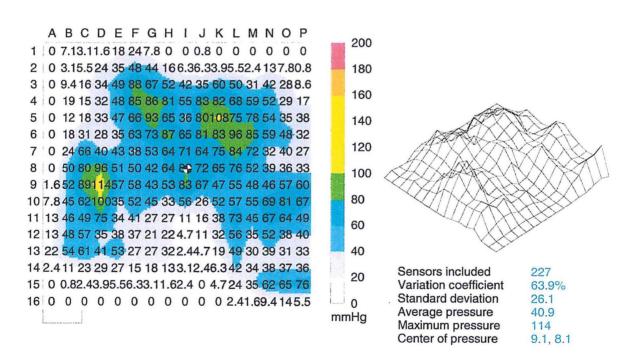


Air cushion.

Subject Two



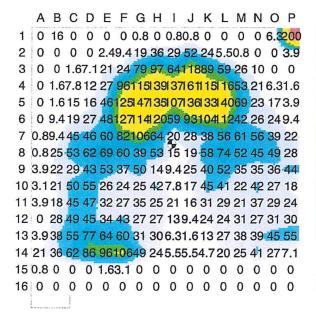
Honeycomb cushion with 10cm block under feet.

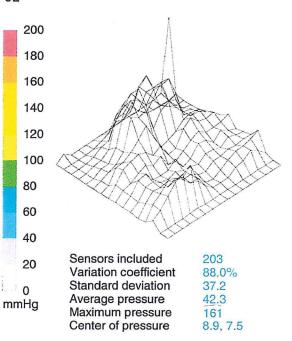


Gel cushion with 10cm block under feet.

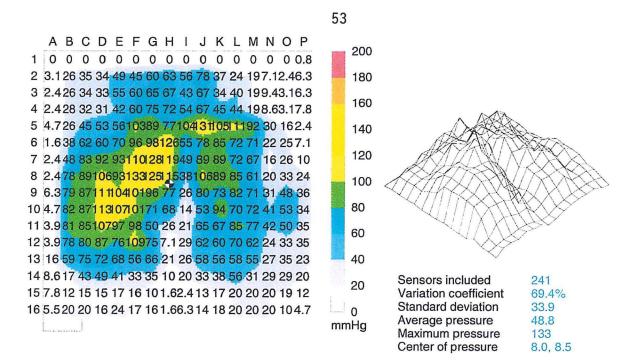
Patient Two continued



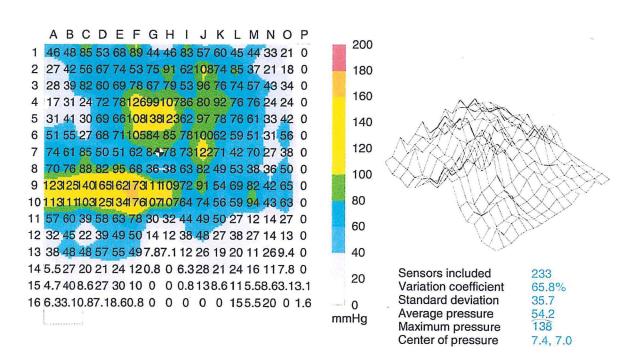




No cushion.

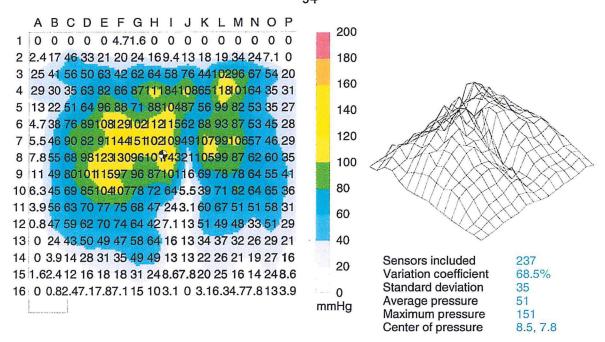


Original, no cushion.

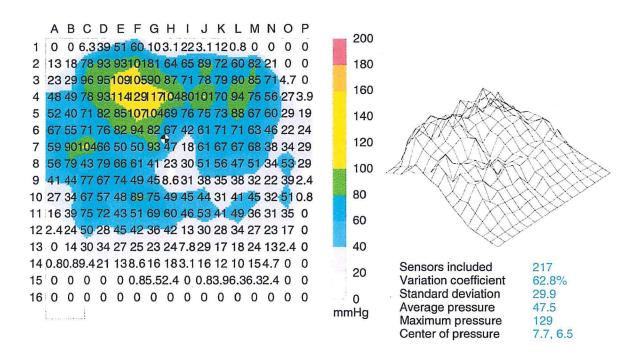


Air cushion with 10cm block under feet. Small wrinkle in pressure-mapping pad location A 9,10 - H 9,10.

Subject Three

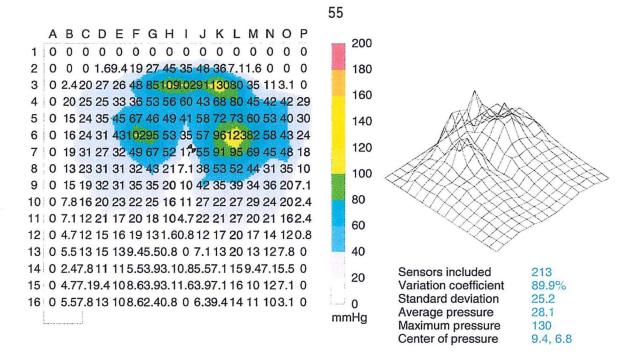


Honeycomb cushion with 10 cm block.

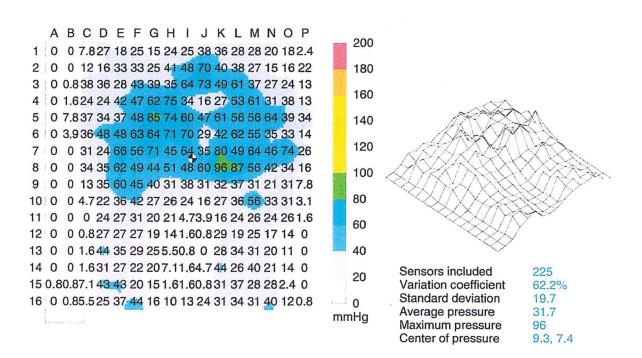


Gel cushion with 10 cm block under feet.

Subject Three continued



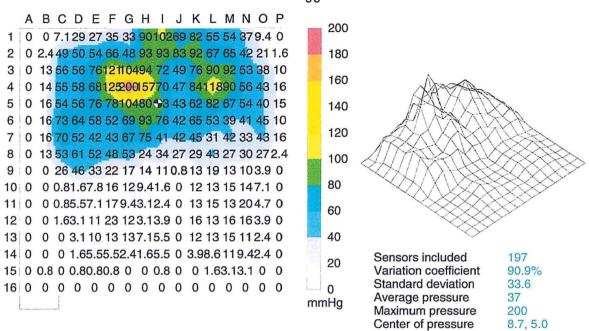
Original cushion honeycomb.



Air cushion.

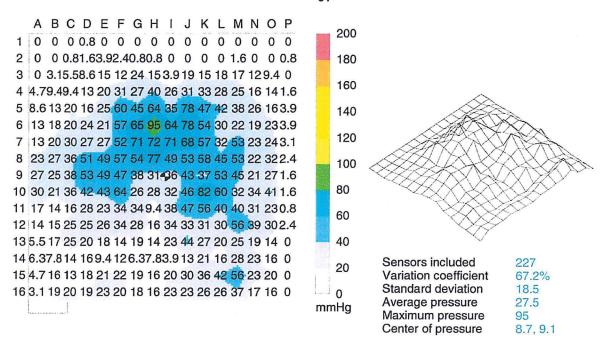
Subject Four



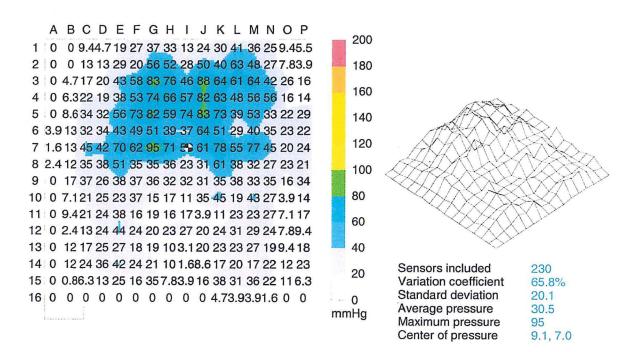


Gel cushion.





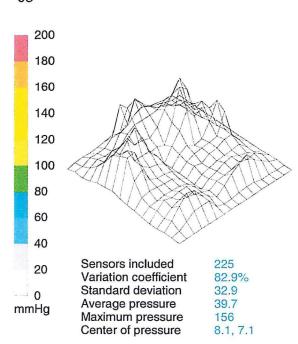
Original cushion. Egg crate.



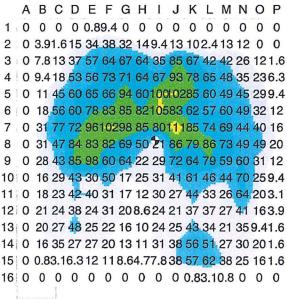
Air cushion.

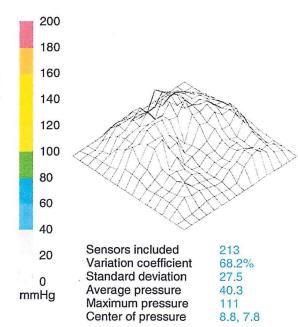
Subject Five





Honeycomb cushion.

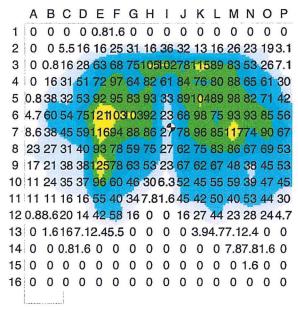


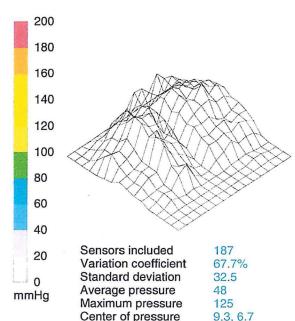


Gel cushion.

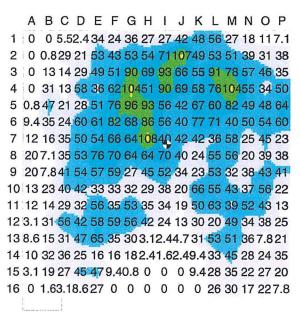
Subject Five continued

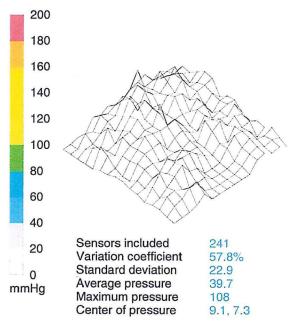






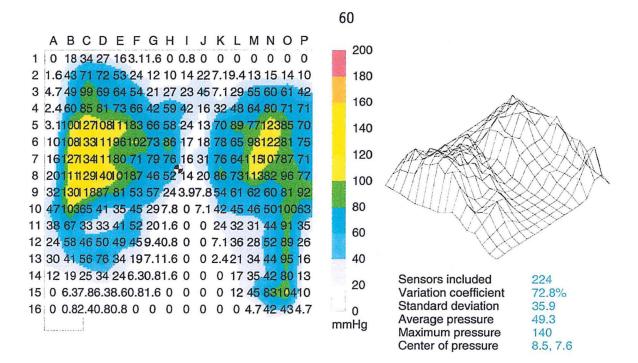
Original cushion.



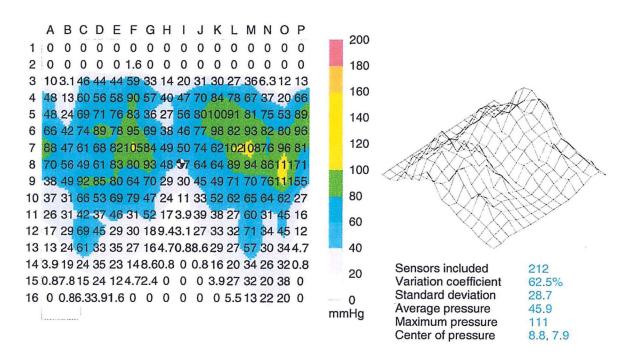


Air cushion.

Subject Six



Honeycomb cushion.



Gel cushion.

Subject Six continued



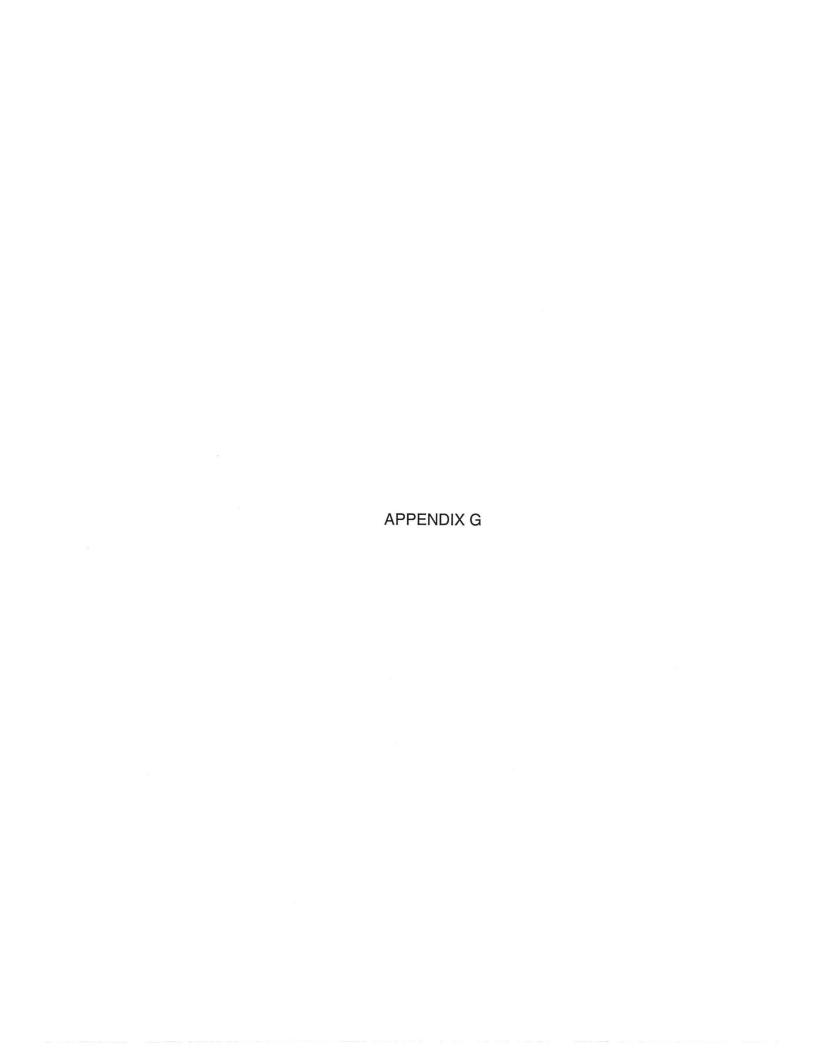
BRADEN SCALE FOR PREDICTING PRESSURE SORE RISK

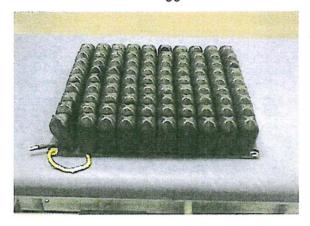
Patient's Name		Evaluator's Name	3	Date of	
				Assessment	1
shilling to respond meaningfully to pressure-re- lated discomfert	Completely Limited: Unresponsive (does not moun, flinch, or grasp) to painful stimuli, due to diminished level of con- sciousness or sedation. OR limited ability to feel pain over most of body surface.		mands, but cannot	mands. Has no sensory deficit which would limit ability to feel or voice pain or discemfur.	
Moisture degree to which skin is exposed to moisture	Constantly Mois: Skin is kept moist almost constantly by perspiration, urine, etc. Dampiness is detected every time patient is moved or turned.	2. Very Moies: Skin is offen, but not always moist. Linen must be changed at least once a shift.	Occasionally Moist; Skin is occasionally moist, requiring an extra linen change approxi- mainly once a day.	Rarely Moist: Skin is usually dry, linen only requires changing at routine intervals	
Activity degree of physical activity	Betfast: Confined to bed	Chairfast: Ability to walk severely limited or non-existent. Camoot bear own weight and/or must be assisted into chair or wheelchair.	3. Walks Occasionally. Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair.	Walks Frequently: Walks outside the room at least twice a day and inside room at least once every 2 hours during waking hours.	
Mobility ability to change and control body position	 Completely immobile: Does not make even slight changes in body or extremity position without assistance. 	 Very Limited: Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently. 	 Slightly Limited: Makes frequent though slight changes in body or extremity position inde- pendently. 	No Limitations: Makes major and frequent changes in position without assistance.	
Nutrition usual food intake pattern	I. Very Poor: Never eats a complete meal. Rarely eats more than 1/3 of my food offered. Eats 2 ser- vings or less of protein (meat or dany products) per day. Takes fluids poorly. Does not take a liquid dietary supplement OR is NPO and/or maintained on clear liquids or IV's for more than 5 days.	Probably Inadequate: Reachy eats a complete meal and generally eats only about 1/2 of any of any food offered. Pro- tein intake includes only 3 servings of meat or or dairy products per day. Occasionally will take a supplement. OR receives less than opti- mum amount of liquid diet or tube feeding.	a total, but will usually	4. Excellent Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.	:
Friction and Shear	1. Problem: Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures or agitation leads to almost constant friction.	Poternial Problem: Moves feebly or requires minumum assistance. During a move skin probably slides to some extent against sheets.	3. No Apparent Problem: Moves in bed and in chair independently and has sufficient muscle strength to lift up completely diring move. Maintains good position in bed or chair at		
NAMES OF THE PROPERTY OF THE P	инариминина и объем в на	TREMITTED AND TRANSPORTED CAMPAGE AND THE PROPERTY OF THE PROP	water of the second	Total Score	-
© Copyright Barbara Braden and No	mcy Bergstrom, 1983				

APPENDIX F

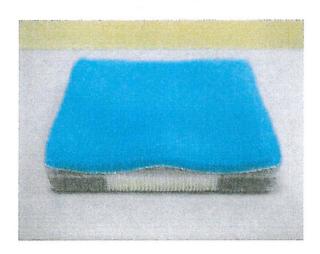
Table 4. Braden Scale Scores for Each Subject

Subject	1	2	3	4	5	6
Sensory Perception	4	4	4	4	4	4
Moisture	3	4	2	4	4	2
Activity	2	3	2	2	2	2
Mobility	3	4	3	2	3	2
Nutrition	3	3	3	3	3	3
Friction and Shear	3	3	1	1	2	1
Total	18	21	15	16	18	14





Air cushion



Honeycomb Cushion



Gel Cushion

Figure 3. Cushions





Wheelchair with leg rests.



Wheelchair without leg rests.



Motorized wheelchair.

Figure 4. Wheelchairs

REFERENCES

- Ferguson-Pell M, Cardi MD. Prototype development and comparative evaluation of wheelchair pressure mapping system. *Assist Technnol*. 1993;5:78-91.
- 2. Takechi H, Tokuhiro A. Evaluation of wheelchair cushions by means of pressure distribution mapping. *Acta Med Okayama*. 1998;52:245-254.
- Levy B. Which way is your tush leaning? Paper presented at: National Seating and Mobility Symposium; July 1997 (revised March 2000).
- 4. Shaw CG. Seat cushion comparison for nursing home wheelchair users.

 Assist Technol. 1993;5:92-105.
- Yuen HK, Garrett D. Comparison of three wheelchair cushions for effectiveness of pressure relief. Am J Occup Ther. 2001;55:470-475.
- Geyer MJ, Brienza DM, Karg P, Trefler E, Kelsey S. A randomized control trial to evaluate pressure-reducing seat cushions for elderly wheelchair users. Adv Skin Wound Care. 2001;14:120-132.
- 7. Gould D, Goldstone L, Gammon J, Kelly D, Maidwell A. Establishing the validity of pressure ulcer risk assessment scales: a novel approach using illustrated patient scenarios. *Int J Nurs Stud.* 2002;39:215-228.
- 8. Ayello EA, Braden B. How and why to do pressure ulcer risk assessment.

 Adv Skin Wound Care. 2002;15:125-133.

- Shapcott N, Levy B. By the numbers: making the case for clinical use of pressure measurement mat technology to prevent the development of pressure ulcers. *Team Rehab Report*. January 1999:16-18, 20-21.
- Rader J, Jones D, Miller L. The importance of individualzed wheelchair seating for frail older adults. *J Gerontol Nurs*. 2000;26:24-32.
- Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Intern Med.* 2001;135:744-751.
- Braden BJ, Bergstrom N. Predictive validity of the Braden scale for pressure sore risk in a nursing home population. Res Nurs Health. 1994;17:459-470.
- 13. Bergstrom N, Braden B, Kemp M, Champagne M, Ruby E. Predicting pressure ulcer risk: a multisite study of the predictive validity of the Braden scale. *Nurs Res.* 1998;47:261-269.
- Lindgren M, Unosson M, Krantz AM, Ek AC. A risk assessment scale for the prediction of pressure sore development: reliability and validity. J Adv Nurs. 2002;38:190-199.
- Clay M. Pressure sore prevention in nursing homes. *Nurs Stand.* 2000;14:45-50.
- Cooper P, Gray D. Comparison of two skin care regimes for incontinence.
 Br J Nurs. 2001;10:S6-S20.

- Xakellis GC, Frantz RA, Lewis A, Harvey P. Cost-effectiveness of an intensive pressure ulcer prevention protocol in long-term care. Adv Wound Care. 1998;11:22-29.
- McCafferty E, Watret L, Brown C. A multidisciplinary audit of patients' seating needs. *Professional Nurse*. 2000;15:715-716.
- Bergstrom N, Bennett MA, Carlson CE, et al. Treatment of Pressure
 Ulcers. Clinical Practice Guideline, No. 15. Rockville, Md: U.S.
 Department of Health and Human Services. Public Health Service,
 Agency for Health Care Policy and Research. AHCPR Publication No. 95-0652. December 1994.
- Kernozek TW, Wilder PA, Amundson A, Hummer J. The effects of body mass index on peak set-interface pressure on institutionalized elderly.
 Arch Phys Med Rehabil. 2002;83:868-871.
- 21. Eldar R. Prevention of pressure sores: a topic for quality of care improvement. *Groat Med J.* 2002;43:361-363.
- Henderson JL, Price SH, Brandstater ME, Mandac BR. Efficacy of three measures to relieve pressure in seated persons with spinal cord injury.
 Arch Phys Med Rehabil. 1994;75:535-539.
- 23. Regan MB, Byers PH, Mayrovitz HN. Efficacy of a comprehensive pressure ulcer prevention program in an extended care facility. *Adv Wound Care*. 1995;8:49-55.